

## I. AMENDMENTS

### AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions and listings of claims in the application:

1-30. (Canceled)

31. (Currently amended) A method for predicting the likelihood that a human colon cancer patient will exhibit a clinically beneficial patient response to treatment with an inhibitor of ErbB1 inhibitor activation, the method comprising:

- a) assaying a normalized level of a predictive RNA transcript in a sample comprising ErbB1-expressing colon cancer cells obtained from said patient, wherein the predictive RNA transcript is the transcript of laminin gamma 2 (LAMC2); [[and]]
  - b) analyzing the normalized level of the LAMC2 transcript; and
  - c) predicting the likelihood of response of the patient to treatment with [[an]] the inhibitor of ErbB1 inhibitor activation based on the normalized level of the LAMC2 transcript, wherein an increased normalized level of LAMC2 RNA transcript correlates with resistance of the colon cancer to treatment with [[an]] the inhibitor of ErbB1 inhibitor activation, wherein the inhibitor of ErbB1 inhibitor activation binds to ErbB1 and is erlotinib, cetuximab, or gefitinib.

32.-34. (Canceled)

35. (Previously presented) The method of claim 31 wherein said sample is a tissue sample.

36. (Previously presented) The method of claim 35 wherein the tissue sample is fixed, paraffin-embedded, or fresh, or frozen.

37. (Previously presented) The method of claim 35 wherein the tissue sample is derived from fine needle, core, or other types of biopsy.

38. (Currently amended) The method of claim 31 further comprising the step of preparing a report comprising a statement whether the patient is likely to respond to treatment with the inhibitor of ErbB1 inhibitor activation.

39. (Canceled)

40. (Withdrawn) A method comprising administering to a human patient an effective amount of an ErbB1 inhibitor that interacts with an ErbB1 receptor, wherein the patient has been diagnosed with an ErbB1-expressing colon cancer and determined to have a normalized level of a laminin gamma 2 (LAMC2) RNA transcript that indicates that the patient will likely respond to treatment with an ErbB1 inhibitor.

41. (Currently amended) The method of claim 31 wherein the normalized level of the LAMC2 RNA transcript is determined using an array comprising polynucleotides hybridizing to a LAMC2 gene immobilized on a solid surface.

42. (Previously presented) The method of claim 41 wherein said polynucleotides are cDNAs.

43. (Previously presented) The method of claim 42 wherein said cDNAs are about 500 to about 5000 bases.

44. (Previously presented) The method of claim 41 wherein said polynucleotides are

oligonucleotides.

45. (Previously presented) The method of claim 44 wherein said oligonucleotides are about 20 to 80 bases long.

46. (Previously presented) The method of claim 45 wherein the array comprises about 330,000 oligonucleotides.

47. (Previously presented) The method of claim 41 wherein said solid surface is glass.

48.-50. (Canceled)

51. (Currently amended) The method of claim 35, wherein RNA is isolated from colon cancer cells present in a fixed, paraffin-embedded tissue by a procedure comprising:

(a) incubating one or more sections of said fixed, paraffin-embedded tissue at a temperature of about 56 °C to 70 °C in a lysis buffer, in the presence of a protease, without prior dewaxing, to form a lysis solution;

(b) cooling the lysis solution to a temperature where the paraffin solidifies, thereby generating a cooled lysis solution; and

(c) isolating the RNA from said cooled lysis solution.

52. (Currently amended) The method of claim 31 further comprising the use of a kit comprising one or more of (1) extraction buffer/reagents for extracting mRNA from a sample and protocol; (2) reverse transcription buffer/reagents and protocol; and (3) quantitative polymerase chain reaction (qPCR) [[qPCR]] buffer/reagents and protocol suitable for performing the method of claim 31.

53.-58. (Canceled)

59. (Previously presented) The method of claim 41, wherein said polynucleotides comprise modified and unmodified polynucleotides.

60. (Currently amended) The method of claim 31, further comprising determining the normalized level of one or more predictive RNA transcripts in said sample, wherein the predictive RNA transcript is the transcript of one or more genes selected from the group consisting of: ErbB3; EREG; ID1; TITF1; CA9; CD44v6; DR5; KRT17; P14ARF; and PLAUR, wherein an increased normalized level of the predictive RNA transcript of one or more of CA9; CD44v6; DR5; KRT17; P14ARF; and PLAUR, indicates that the patient will show a decreased likelihood of response to treatment with the ErbB1 inhibitor, and an increased normalized level of the predictive RNA transcript of one or more of ErbB3; EREG; ID1; and TITF1 indicates that the patient will show an increased likelihood of response to treatment with the inhibitor of ErbB1 inhibitor activation.

61. (Canceled)

62. (Previously presented) The method of claim 31, further comprising determining the normalized level of a predictive RNA transcript of KRT17 in the sample.

63. (Canceled)

64. (Withdrawn) A method comprising administering to a human patient an effective amount of an ErbB1 inhibitor that interacts with an ErbB1 receptor, wherein the patient has been diagnosed with an ErbB1-expressing cancer and has been determined to have a normalized level of a laminin gamma 2 RNA transcript that

indicates that the patient will likely respond to treatment with an ErbB1 inhibitor.

65. (Canceled).

66. (New) A method for predicting the likelihood that a human colon cancer patient will exhibit a clinically beneficial patient response to treatment with an inhibitor of ErbB1 activation, the method comprising:

- a) assaying a normalized level of a predictive RNA transcript in a sample comprising ErbB1-expressing colon cancer cells obtained from said patient, wherein the predictive RNA transcript is the transcript of laminin gamma 2 (LAMC2);
- b) analyzing the normalized level of the LAMC2 transcript; and
- c) predicting the likelihood of response of the patient to treatment with the inhibitor of ErbB1 activation based on the normalized level of the LAMC2 transcript, wherein an increased normalized level of LAMC2 RNA transcript correlates with resistance of the colon cancer to treatment with the inhibitor of ErbB1 activation, wherein the inhibitor of ErbB1 activation is a monoclonal antibody that binds to ErbB1.

67. (New) The method of claim 66, wherein the monoclonal antibody is cetuximab.

68. (New) The method of claim 66, wherein said sample is a tissue sample.

69. (New) The method of claim 68, wherein the tissue sample is fixed, paraffin-embedded, or fresh, or frozen.

70. (New) The method of claim 68, wherein the tissue sample is derived from fine needle, core, or other types of biopsy.

71. (New) The method of claim 66, further comprising the step of preparing a report comprising a statement whether the patient is likely to respond to treatment with the inhibitor of ErbB1 activation.
72. (New) The method of claim 66, wherein the normalized level of the LAMC2 RNA transcript is determined using an array comprising polynucleotides hybridizing to a LAMC2 gene immobilized on a solid surface.
73. (New) The method of claim 72, wherein said polynucleotides are cDNAs.
74. (New) The method of claim 73, wherein said cDNAs are about 500 to about 5000 bases.
75. (New) The method of claim 72, wherein said polynucleotides are oligonucleotides.
76. (New) The method of claim 75, wherein said oligonucleotides are about 20 to 80 bases long.
77. (New) The method of claim 72, wherein the array comprises about 330,000 oligonucleotides.
78. (New) The method of claim 72 wherein said solid surface is glass.
79. (New) The method of claim 68, wherein RNA is isolated from colon cancer cells present in a fixed, paraffin-embedded tissue by a procedure comprising:
- (a) incubating one or more sections of said fixed, paraffin-embedded tissue at a temperature of about 56 °C to 70 °C in a lysis buffer, in the presence of a protease, without prior dewaxing, to form a lysis solution;
  - (b) cooling the lysis solution to a temperature where the paraffin solidifies, thereby

generating a cooled lysis solution; and

- (c) isolating the RNA from said cooled lysis solution.

80. (New) The method of claim 66, further comprising the use of a kit comprising one or more of (1) extraction buffer/reagents for extracting mRNA from a sample and protocol; (2) reverse transcription buffer/reagents and protocol; and (3) quantitative polymerase chain reaction (qPCR) buffer/reagents and protocol suitable for performing the method of claim 66.

81. (New) The method of claim 72, wherein said polynucleotides comprise modified and unmodified polynucleotides.

82. (New) The method of claim 66, further comprising determining the normalized level of one or more predictive RNA transcripts in said sample, wherein the predictive RNA transcript is the transcript of one or more genes selected from the group consisting of: ErbB3; EREG; ID1; TITF1; CA9; CD44v6; DR5; KRT17; P14ARF; and PLAUR, wherein an increased normalized level of the predictive RNA transcript of one or more of CA9; CD44v6; DR5; KRT17; P14ARF; and PLAUR, indicates that the patient will show a decreased likelihood of response to treatment with the ErbB1 inhibitor, and an increased normalized level of the predictive RNA transcript of one or more of ErbB3; EREG; ID1; and TITF1 indicates that the patient will show an increased likelihood of response to treatment with the inhibitor of ErbB1 activation.

83. (New) The method of claim 66, further comprising determining the normalized level of a predictive RNA transcript of KRT17 in the sample.